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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,793	04/14/2004	Alfred Z. Abuhamad	113019.164US1	4664
24395	7590	08/04/2006	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP 1875 PENNSYLVANIA AVE., NW WASHINGTON, DC 20004			JAWORSKI, FRANCIS J	
		ART UNIT	PAPER NUMBER	
				3768

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/823,793	ABUHAMAD, ALFRED Z.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jaworski Francis J.	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 29 November 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1 - 17 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1 - 17 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 24 August 2004 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/29/04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

### *Specification*

- 1) The specification in para [0014-15] indicates that the invention is directed towards operator-independent examination of fetal, neonatal and/or adult organs. Elsewhere in para [0020] and para [0037] applicant has indicated that the invention is applicable to any patient and with regards to any organ characterizable by anatomic relationships. Therefore the Examiner's understanding is that while fetal scanning is dependent on fetal position and while neonatal and adult cardiac scanning for example are dependent upon access to view windows between ribs and across pulmonary air spaces and so such fetal,neonatal and adult studies are all vulnerable to technician skill deficiencies and therefore enhanced by operator-independent machine assistance, pediatric and adolescent applications are in fact embraced by terminology 'any human patient'.  
2) The terms 'standard/standardized' and 'reference' with respect to scan planes overlap insofar as a reference view may be a standard one (such as a view having a well-defined clinical meaning) and a standard view may in turn serve as a reference view. Additionally:

What constitutes a 'standard' or 'standardized' view plane is also subjective in that it can pertain to what is customary on the individual level (As in ' He has his own standard way of doing things.') and it may also merely pertain to that which is reproducible (as for example when an athlete sets a standard in competition.)

What constitutes a 'reference' view is relative since an initial and selectable view chosen de novo during a study may serve as a reference, or alternatively a fixed and predetermined view may constitute a reference during a study.

It is necessary to entertain the breadth of reasonable terminology interpretation here since at least part of the patent disclosures applied as prior art below are described from the perspective of graphics processing engineering as opposed to a perspective which details a specific clinical application, in which former case what is likenable to a standard or a reference is generalized and abstract when referenced to a purely medical context yet all of these disclosures are directed to improving ease and quality of medical imaging study.

3) In the prior art an anatomic 'reference' obtained for the functioning of a three-dimensional imager need not be an image, and if the anatomic reference is in fact an image it need not be the basis for display of further images. In McMorrow et al (US6905468) for example which is directed to three-dimensional evaluation of abdominal aortic aneurysm for output of a diameter measurement, the initial reference for the 3D ultrasound study may be merely a Doppler line, col. 3 lines 40 – 67, or alternatively a power Doppler locator image in order to speed the calculation of maximum aneurysm diameter (col. 4 lines 36 – 53) without the locator image serving to define further images.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7 – 8, and 14 –17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark (US6174285, of record in applicant's specification), further in view of Arling (US5872571).

Clark is directed to a method and system architecture and a view display procedure set stored in operating memory 36 using code executable under control of CPU 34 which acts to acquire ultrasound 3D image data for a heart, and utilizes a reference positioning visualized as a 2-D scan plane by the user in order to define inter alia a further two or more pre-set views once reference positioning is achieved, see col. 3 line 21 – 5 line 9. Clark does not however 'utilize data defining a reference plane...to define at least one other plane'. That is, as noted in point 3) above, the full data of a view need not be used in order to provide a reference to the system nor does the pre-set 2-D reference plane view of step 50 necessarily provide data for the further pre-set views as opposed to merely assuring aim before triggering a free-running, non-contingent view rendering process.

However it would have been obvious in view of Arling to provide the further pre-selected views of Clark by the aforementioned procedure increment of 'utilizing.' Specifically, in the latter the reference plane serves to determine the angular offsets of the additional view planes, see col. 3 lines 35 – 58, and for purposes similar to Clark of

Note in this regard that the rejection argument in effect represents two variations of an argument in the sense that the combined teachings would suggest that a further view plane having a fixed geometry to the reference plane be simultaneously displayed as in Arling, or that a further anatomic pre-set view be displayed using the reference positioning plane as a basis for generating a further view. (claims 1, 7 – 8, 16 - 17).

Such further view planes derived based upon the positioning location in Clark are characterizable as standardized since they are reproducible, see also discussion of point 2) supra. (Claims 14 – 15).

Claims 2, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark in view of Arling as applied to claim 1 above, and further in view of Kamiyama (US6290648). Whereas the former are silent as to fetal heart observation since Clark is non-specific in this regard with respect to Figs. 1 – 2 and attendant discussion, it would have been obvious in view of Kamiyama col. 1 lines 22 – 30 to examine fetal hearts as analogous to adult hearts where a multiple view format is being used, see col. 2 lines 1 – 18 of the latter. Note that whereas Kamiyama is otherwise user – driven wrt this col. 2 passage, under an alternative interpretation Kamiyama is also compatible with a format which automatically uses the reference image to define a further image without registry orienting of multiple view planes by a user observing a mark. That is, col. 2 lines 18 – 31 considered together with col. 8 lines 3 – 40 suggests that such endeavor as orienting a further view with respect to a reference view may also include position matching (where

the further view is a view after an artifact movement) or tumor monitoring (where the further view is of the same lesion at a later date), there being nothing in applicant's base claim which limits the other plane defined by the reference plane to be not-the-same-view-direction. (claim 2).

Otherwise Kamiyama stores lesion pathologies for comparison and identification of abnormal structures. (Claim 11)

Otherwise Clark's heart images include the left and right-sided outflow tracts in Figs. 2a and 2b as well as the aortic arch in Fig. 1a. (claims 3 – 4).

Claims 5 – 6, 9 - 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark in view of Arling as applied to claim 1 above, and further in view of Detmer(US6443896) and Coleman et al (US6306089). Whereas the former are silent as to fetal imaging, it would have been obvious in view of Detmer col. 1 lines 20 – 24 and 44, col. 3 line 64 – col. 4 line 65 to use multi-planar imaging for general obstetric as opposed to cardiology use, whereupon alternative to cardiac calculations as per Detmer col. 5 top one would use obstetric calculations as per Coleman et al col. 5 top in accordance with this usage.(Claims 5 – 6).

In either case the calculated result is characterizable as a 'medical evaluation'. (Claim 9).

Otherwise the image recognition software described in Clark col. 5 top is applicable. (claim 10).

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark in view of Arling as applied to claim 1 above, and further in view of Avila et al

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(US6413219) considered in light of applicant's prior art admissions in para [0008, upper half] since whereas the former although real-time in operation are silent as to orthogonal cut planes for the presented views, it would have been obvious in view of Avila et al to provide same for full multiplanar characterization, Avila et al being likenable to the technology discussed in applicant's specification where the orthogonal views are referenced to the human body axis.

Frisa et al (US6709394) is directed to a biplanar imaging technique in which both the orientation and tilt of the second plane with respect to the reference plane may be pre-determined.

Kamada et al (US5776067) is directed to affine transformation practiced on bi-planar images.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

06-14-06



Francis J. Jaworski  
Primary Exr  
AU 3768